



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/641,983	08/17/2000	Michael L. Lehrman	ILIF01-00056	6192

23990 7590 04/07/2003

DOCKET CLERK
P.O. DRAWER 800889
DALLAS, TX 75380

EXAMINER

WEISS JR, JOSEPH FRANCIS

ART UNIT	PAPER NUMBER
----------	--------------

3761

DATE MAILED: 04/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/641,983

Applicant(s)

Lehrman et al.

Examiner

Joseph Weiss

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 21, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

Art Unit: 3761

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-2, 4, 6, 11-12, 14 & 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Shannon, Jr. et al. (US 5123425).

In regards to claims 1 & 11, Shannon discloses an apparatus for terminating an obstructive sleep apnea even before cessation of breath occurs comprising at least one microphone (24 and supporting text) which detects breathing sounds and which generates signals representative of such; a controller (20) coupled to the microphone capable of receiving such breathing sound signals and identifying signals indicative of the onset of obstructive sleep apnea/(e.g a partially occluded airway) event before cessation of breathing occurs and capable of generating an alarm signal (col. 3 lines 25-50), and a stimulus generator (26 & 28 and supporting text) capable of receiving such alarm signals creating a stimulus to cause said person to move in a manner that causes said obstructive sleep apnea/(e.g. partial occlusion) event to terminate before cessation of breathing occurs.

In regards to claims 2 & 12, Shannon discloses the use of an electrical current source (note the use of electrodes, an electrical current source).

Art Unit: 3761

In regards to claims 4 & 14, Shannon discloses the use of an electrical current source (note the use of electrodes, an electrical current source).

In regards to claims 6 & 16, Shannon discloses the use of at least one filter (204) for filtering the signal, the filtered signal being indicative of breathing patterns and discerned by the controller as being a indicative of the onset of obstructive sleep apnea/(e.g. partially occlude airway)to include the capability to detect patterns of said person that occurs at the onset of an obstructive sleep apnea even before cessation of breathing occurs.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 7-8, 10, 17-18, 20-22 & 24-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shannon.

In regards to claims 7 & 17, Shannon discloses that an air flow sensor can be utilized with the device, thus one of ordinary skill in the art would consider applicant's use of an air flow sensor with the instant device to be an obvious modification to the device of the prior art. (Col. 3, line 30-35).

In regards to claims 8 & 18, Shannon discloses the instant application's invention, to include the capability to detect patterns of said person that occurs at the onset of an obstructive

Art Unit: 3761

sleep apnea even before cessation of breathing occurs, except for an express recitation of the use of “software.” However, software is nothing more than a series of commands in an algorithm to be executed a given way, based upon input, feedback, conditions and events. The electronic’s module of Shannon performs such algorithmic tasks and thus would be viewed by one of skill in the art as being “programmed” and hence to be comprised of what would be understood as “software.” Accordingly, such a limitation under a standard of obviousness would not distinguish the instant application’s claimed invention over that of the prior art. (See fig 7 and supporting text in col. 4 lines 5-42).

In regards to claims 10 & 20, operation during $\frac{1}{2}$ of the breathing cycle, the device of Shannon is fully capable of being operated in a manner wherein the controller operates the device for only “one half” of a respiratory cycle.

In regards to method claims 21-22 & 24-29, one of ordinary skill in the art would appreciate that the method steps claimed in the instant application would naturally flow from the device disclosed in the prior art as noted above and therefore are rejected herein above with respect to claims 1-2, 4, 6-8, 10-12, 14, 16-18 & 20.

5. Claims 9 & 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shannon as applied to claims 8 & 18 above, and further in view of Schecter et al (US 5058600).

In regards to claims 9 & 19, Shannon substantially discloses the instant application’s claimed invention to include the capability of detecting a breathing signal associated with the onset of an obstructive sleep apnea event, but does not explicitly disclose using software with Fast

Art Unit: 3761

Fourier Transform (FFT) analysis. However, Schecter disclose such (Note abstract statement that acoustic signals are processed using FFT). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Schecter and used them with the device of Shannon. **The suggestion/motivation for doing so would have been to effectively process the acoustical data for diagnostic analysis.** Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

~~§~~ 23

6. Claims 3 & 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shannon as applied to claims 1 & 11 above, and further in view of Lambert (US 5652566).

- In regards to claims 3 & 13, Shannon substantially discloses the instant application's claimed invention, but does not explicitly disclose the use of a vibrator or a sound generator. However, Lambert disclose such (24). The references are analogous since they are from the same field of endeavor, the medical monitoring arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Lambert and used them with the device of Shannon. The suggestion/motivation for doing so

Art Unit: 3761

would have been to provide additional/redundant alarm systems, insuring the user is stimulated. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to method claims 23, one of ordinary skill in the art would appreciate that the method steps claimed in the instant application would naturally flow from the device disclosed in the prior art as noted above and therefore are rejected herein above with respect to claims 3 & 13.

7. Claims 5 & 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shannon as applied to claims 1 & 11 above, and further in view of Teodorescu et al (US 6011477).

In regards to claims 5 & 15, Shannon substantially discloses the instant application's claimed invention to include the capability to detect patterns of said person that occurs at the onset of an obstructive sleep apnea even before cessation of breathing occurs, but does not explicitly disclose a remote base station. However, Teodorescu disclose such (28). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Teodorescu and used them with the device of Shannon. The suggestion/motivation for doing so would have been to give the user more

Art Unit: 3761

range/freedom of movement during use of the device. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

Response to Arguments

8. Applicant's arguments filed 21 Jan 03 have been fully considered but they are not persuasive.

In regards to the objection to the specification, applicant's amendment is proper and responsive and resolves the issue, therefore the objection is withdrawn.

In regards to the 35 USC 102 & 103 rejections, applicant's amendment is proper and responsive, but does not resolve the issues, therefore the rejections are retained, as modified above in response to applicant's amendments.

Note generally:

Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

Applicant's arguments do not comply with 37 CFR 1.111© because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of

Art Unit: 3761

the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections.

In response to the 35 USC 102 arguments:

At the outset the examiner notes that applicant points to no empirical differences in structure between the prior art device and the instantly claimed invention. Instead applicant points to several “capabilities” “functions” “intended uses/results” of the very same structure that the prior art discloses, and then asserts that those same features in the prior art cannot perform those very same “capabilities” “functions” “intended uses/results.” Please explain this paradox?

In response to applicant's argument that the intended use/result language of “before cessation of breath,” a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Applicant points to no structure in his invention that flows as a distinction from the device of the prior art.

There is no teaching in the prior art that the airway must be fully obstructed before it will act upon ameliorating an apneic event.

Art Unit: 3761

Before cessation of breath does not correlate to the airway not being obstructed, there is a gap in applicant's logic in asserting that this language to one of ordinary skill in the art would understand that such language inherently means the airway is not obstructed. But instead it at best can only arguably mean the airway is not "fully obstructed" to cause cessation of breath.

The plain language of applicant's claim pre-supposes the existence of a sleep apnea event, i.e. obstruction, not just onset. Note the language of claim 1, "An apparatus for TERMINATING AN OBSTRUCTIVE SLEEP APNEA EVENT" If the airway that applicant's invention is acting upon is not obstructed, then what is applicant's invention terminating? By definition an obstructive sleep apnea event involves airway obstruction.

The Shannon reference makes no such correlation to onset empirically meaning the airway is completely obstructed, contrary to applicant's assertion that this is clear. None of the fragments applicant points suggest, let alone clearly state this correlation of terms. Therefore applicant's arguments are not persuasive, and the rejection is retained as noted above.

In regards to the 35 USC 103 rejections:

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

Art Unit: 3761

4. Considering objective evidence present in the application indicating obviousness or nonobviousness. The rejections meet these criteria.

The before cessation of breath language is an intended result as noted previously & presents no additional structure, see the 102 arguments above.

Applicant concludes without a reasoned basis that Shannon does not analyze breathing sounds, which is contrary to the disclosure of Shannon as read by one of ordinary skill in the art.

The apparatus of Schecter is not relevant to the objection, just its teaching of using FFT to detect breathing sounds as one of ordinary skill in the prior art would appreciate it could be used in light of state of the art and the teachings.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). Please read the rejection.

Regarding the 103 rejection of Lambert again the examiner notes, The before cessation of breath language is an intended result as noted previously & presents no additional structure, see the 102 arguments above.

Art Unit: 3761

Regarding the need for a monitor, the fragment of Lambert applicant points to is merely illustrative of the many needs for monitoring, please read the reference as a whole.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). Please read the rejection.

Regarding the 103 rejection of Teodoreescu again the examiner notes, The before cessation of breath language is an intended result as noted previously & presents no additional structure, see the 102 arguments above.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). Please read the rejection.

Art Unit: 3761

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Joseph F. Weiss, Jr., whose telephone number is (703) 305-0323. The Examiner can normally be reached from Monday-Friday from 8:30 AM to 4:30 PM. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Aaron Lewis, can be reached at telephone number (703) 308-0716. The official fax number for this group is (703) 305-3590 or x3591. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858.



Joseph F. Weiss, Jr.

April 3, 2003



WEILUN LO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700